

REMARKS

Claims 1, 7, 19, 20, 27, and 38 were previously pending in the present application. The present Amendment adds new claims 39 and 40. Thus, upon entry of the present Amendment, claims 1, 7, 19, 20, 27, and 38-40 will be pending.

Applicants note with appreciation the telephonic interview granted by the Examiner on February 11, 2009. During the interview, Applicants' representatives stressed that the primary reference (Baker) being cited against the current claims contains a vast number of possible compounds, and thus cannot disclose or suggest the very specific compounds found in the narrow weight ranges of the present claims. Applicants also stressed that the specification of the present application establishes the criticality of the claimed weight ranges submitted in the Amendment filed January 26, 2009, and the Examiner stated that these amendments gave further support to the arguments of criticality. In response to the Interview Summary mailed on February 17, 2009, Applicants respectfully submit that it was the solvent, not a surfactant, which Applicants stressed was a critical element of Baker not found in the present claims. Applicants otherwise agree with the summary of the interview as stated in the Interview Summary.

Claims 1, 7, 19, 20, 27, and 38 have been rejected under 35 U.S.C. §103(a) as being unpatentable over United States Patent No. 6,559,189, to Baker, Jr. et al., ("Baker") in view of United States Patent No. 6,335,012, to Fischetti et al. ("Fischetti") Claims 1 and 20 are independent. Applicants respectfully traverse.

Claim 1 is directed to a tampon comprising an absorbent material and a composition disposed in the absorbent material. The composition comprises at least one antibacterial agent in an amount of about 0.10 wt% to about 2.5 wt% of the total weight of the tampon, and at least one finishing agent in an amount of about 2.5 wt% of the total weight of the tampon. The antibacterial agent is a mixture of alkyl dimethyl benzylammonium chloride and alkyl dimethyl ethylbenzylammonium chloride, and the at

least one finishing agent is one or more polyoxyethylene fatty acid esters. The composition has synergistic antibacterial properties effective to neutralize the production of TSST-1 toxin and reduce *Staphylococcus aureus* bacteria growth.

Baker is directed to compositions and methods for decreasing the infectivity, morbidity, and rate of mortality associated with a variety of pathogenic organisms and viruses. (Abstract) In one of the example compositions cited in the Office Action, Baker discloses a nanoemulsion comprising Tween 60 or other members of the Tween family, and a quaternary ammonium compound such as N-alkyl dimethylbenzyl ammonium chloride. The Tween 60 may be present in an amount of 0.5 – 2%, and the quaternary ammonium compound in an amount of 0.5 – 2%, each based on the weight of the composition. (col. 30, l. 29-48)

Fischetti is relied on by the Office Action to show that polyoxyethylene fatty acid ester and polyoxyethylene sorbital esters are functional equivalents. The Office Action takes official notice that the two are equivalent. Applicants respectfully disagree.

Even assuming, *arguendo*, that the Office Action's taking of official notice with respect to the equivalence of polyoxyethylene fatty acid ester and polyoxyethylene sorbital esters is correct, the combination of Baker and Fischetti fails to disclose the tampon of claim 1. The Office Action states, on p. 4, that since the general conditions of the claim with respect to the antibacterial agent are disclosed in the prior art, "discovering the optimum or workable ranges involves only routine skill in the art." This assertion is repeated on p. 5 with respect to the claimed at least one finishing agent.

However, according to MPEP §2144.05(II)(A), such a determination of obviousness may be overcome by a showing that the claimed ranges are critical. Applicants have done just that in the present application, in Table 1, which spans pp. 12-13 of the present specification. The two compositions having a concentration of 2.5 wt% of at least one finishing agent (e.g., Tween 20), as recited in claim 1, exhibit vastly improved TSST-1 reduction, when compared to compositions having 0.25 wt% of

Tween 20, which is outside the claimed range. These results were not contemplated by Baker or Fischetti. There is no discussion of a critical range of the Tween 20 in either reference. Baker, in particular, only discloses general weight ranges of possible components based on the total weight of the composition. Since it barely mentions the use of a tampon, it does not appreciate the criticality of the claimed amount of antibacterial agent and finishing agents based on the total weight of a tampon, as recited in claim 1. See MPEP §2144.05(III). Applicants respectfully submit that this showing of criticality clearly overcomes the Office Action's determination of obviousness.

Therefore, claim 1 is patentable over Baker in view of Fischetti under 35 U.S.C. §103(a), as are claims 7 and 19, which depend therefrom.

Claim 20 recites a method of inhibiting the production of TSST-1 toxin by exposing TSST-1 toxin-producing *Staphylococcus aureus* bacteria to a tampon. The tampon comprises an absorbent material and a composition. The composition has at least one antibacterial agent in an amount of about 0.10 wt% to about 2.5 wt% of the total weight of the tampon, , and at least one finishing agent in an amount of about 2.5 wt% of the total weight of the tampon. The antibacterial agent is a mixture of alkyl dimethyl benzylammonium chloride and alkyl dimethyl ethylbenzylammonium chloride, and the at least one finishing agent is one or more polyoxyethylene fatty acid esters.

As previously discussed with respect to claim 1, the combination of Baker and Fischetti fails to disclose or suggest the composition of claim 20. Therefore, claim 20 is patentable over Baker in view of Fischetti under 35 U.S.C. §103(a), as are claims 27 and 38, which depend therefrom.

Applicants respectfully submit that the rejection of claims 1, 7, 19, 20, 27, and 38 under 35 U.S.C. §103(a) as being unpatentable over Baker in view of Fischetti has been overcome. Applicants respectfully request that it be withdrawn.

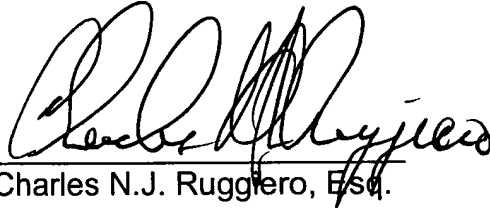
New claims 39 and 40 depend from claims 1 and 20, respectively, and recite that the claimed compositions consist essentially of the recited components.

As discussed during the telephonic interview on February 11, 2009, all compositions of Baker recite at least one additional critical component that materially affects the basic and novel characteristics of the invention disclosed in Baker. For example, the composition cited in the Office Action for the claimed weight ranges contains a mixture of "oils, detergents, solvents, and cationic halogen-containing compounds in addition to several ions that enhance [the compositions'] biocidal activities." (col. 30, l. 21-25, emphasis added)

By contrast, claims 39 and 40 exclude any compounds, other than the claimed mixture of alkyl dimethyl benzylammonium chloride and alkyl dimethyl ethylbenzylammonium chloride, and one or more polyoxyethylene fatty acid esters, that neutralize the production of production of TSST-1 toxin and reduce *Staphylococcus aureus* bacteria growth. Thus, many of the compounds listed as key ingredients in Baker are excluded from the compositions of claims 39 and 40, since Baker specifically states that they are added for their "biocidal activity." This is further support of the patentability of these claims.

Therefore, Applicants respectfully submit that the present application is in condition for allowance. The issuance of a Notice of Allowance is earnestly solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Charles N.J. Ruggiero", written over a horizontal line.

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